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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/031,087	02/26/1998	CHIH-SHENG CHIANG	054769-2001	8207

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FOLEY & LARDNER LLP
P.O. BOX 80278
SAN DIEGO, CA 92138-0278

EXAMINER	
TUNG, JOYCE	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/031,087	CHIANG ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2-11 and 14-22*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-11 and 14-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The applicant's amendment filed 12/29/2005 has been entered. Claims 2-11 and 14-22 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/29/2005 has been entered.

2. Applicant's arguments with respect to claims 2-11 and 14-22 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2-11, and 14-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 2-11 and 14-22 are vague and indefinite because of the phrase "can hybridize". It is unclear whether or not the first probe hybridizes to the target nucleic acid and the second probe hybridizes to the first probe. Clarification is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 3-6, 8-10, 20 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Heller et al. (5,849,489, issued December 15,1998).

Heller et al. disclose a method of incorporating the property of an extended nonradiative energy transfer process into arrangement of synthetic nucleic acid (See column 4, lines 23-29). The method is applied to homogeneous hybridization reaction in which a specific nucleic acid sequence is amplified via a polymerase chain reaction (See column 21, lines 13-20). The method comprises using a first probe, which is an acceptor (AO) of 15-50 nucleotides in length, and labeled with Texas Red at or near its 5' terminal and is complementary to the portion of DNA target sequence (See column 27, lines 55-59). The method also comprises using a second probe, which is a quencher oligonucleotide (QO) of 10-45 nucleotides in length and labeled with Reactive Red 4 near its 3' terminal. The quencher oligomer is complementary to the acceptor oligomer, but is 5 to 10 bases shorter, when it is hybridized to the acceptor oligomer the Reactive red 4 group is within 1 to 5 bases of the Texas Red group, causing complete quenching of the Texas Red fluorescence (See column 27, lines 60-67). Any unhybridized acceptor oligomer re-hybridizes with quencher oligomer. The target DNA has organized with the donor oligonucleotide and the acceptor oligonucleotide for efficient extended energy transfer to the

Texas Red group. The target DNA is quantified by fluorescent analysis (See column 28, lines 21-26).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 2, 11 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (5,849,489, issued December 15,1998) as applied to claims 3-6, 8-10, 20 and 22, further in view of Morrison et al. (Analytical Biochemistry, 1989, Vol 183, pg. 231-244).

The teachings of Heller et al. are set forth in section 5 above. Heller et al. do not disclose a thermostable polymerase used in the amplification.

Morrison et al. disclose a DNA homogeneous assay using competitive hybridization (See pg. 231, the Abstract) in which a target DNA is amplified with a thermostable polymerase (See

pg. 235, column 1, second paragraph). Morrison et al. also disclose that the thermal dissociation of complementary labeled DNA strands was monitored by measuring the fluorescein emission intensity as the temperature was increased from a temperature below the melting temperature to a temperature above the melting temperature (See pg. 237, column 2).

One of ordinary skill in the art would have been motivate to apply the thermostable polymerase of Morrison et al. in the method of Heller et al. because the combination of the hybridization sensitive probe and PCR amplification provided combined sensitivity, speed, specificity and simplicity (See pg. 244, column 1). It would have been prima facie obvious to have a thermostable polymerase used in the amplification.

9. Claims 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (5,849,489, issued December 15,1998) as applied to claims 3-6, 8-10, 20 and 22, further in view of Hiroaki et al. (EP 0461 863 A1).

The teachings of Heller et al. are set forth in section 5 above. Heller et al. do not disclose that the target polynucleotide comprises hepatitis C virus genome, the probe has the sequence of SEQ ID NO: 3 and 4 and the primer has the sequence of SEQ ID NO: 1 and 2.

Hiroaki et al. disclose a highly sensitive detection system for NANB hepatitis virus at its gene lever and oligonucleotide primer used for the system (See pg. 2, lines 31-32). The NANB hepatitis is termed hepatitis C virus (HCV) (See pg. 2, lines 10-12). A nucleotide sequence of the 5' noncoding region from HC-J1 has been identified (See pg. 3. lines 4-32). The primers used in the highly sensitive detection system for HCV corresponding to the part of the 5' noncoding region of HCV are disclosed (See pg. 3, lines 38-42). The nucleotide of the 5' noncoding region comprises SEQ ID NO: 1 and 3 and the complementary sequence of SEQ ID NO 2 and base pair 1-17 of SEQ ID NO: 4 (See pg. 7, lines 11-21 and pg. 8, lines 15-19).

One of ordinary skill in the art would have been motivated to apply these nucleic acid sequences disclosed by Hiroaki et al. as probes and primers in the method of Heller et al. for the specific detection of the target polynucleotide, hepatitis C virus because these nucleic acid sequences provide a highly sensitive detection system for NANB hepatitis virus at its gene lever (See pg. 2, lines 31-32). It would have been prima facie obvious to apply SEQ ID NO: 1 and 2 as primers and SEQ ID NO: 3 and 4 as probes in the method of Heller et al. for the detection of the target polynucleotide, hepatitis C virus.

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (5,849,489, issued December 15,1998) as applied to claims 3-6, 8-10, 20 and 22 above, and further in view of Meade et al. (See 5,824,473, issued October 20, 1998).

The teachings of Heller et al. are set forth in section 5 above. Heller et al. do not disclose the fluorophore is on the 3' terminal of the first probe and the quencher is on the 5' terminal of the second probe.

Meade et al. disclose the selective modification of nucleic acid at specific site with redox active moieties (See column 5, lines 33-36). The moieties can be switched either on 5' terminal or 3' terminal (See fig. 1 and 2, column 15, lines 41-52).

One of ordinary skill in the art would have been motivated to apply the method of Meade et al. to make the probes with the switched moieties on the terminal of the probes in the method of Heller et al. for monitoring nucleic acid amplification because the method of Meade et al, is used to make an entirely new class of bioconductors and photoactive probes. It would have been prima facie obvious to switch the moieties on the probe as recited in the claim.

11. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (5,849,489, issued December 15,1998) as applied to claims 3-6, 8-10, 20 and 22, further in view of Walker et al. (5,270,184).

The teachings of Heller et al. are set forth in section 5 above. Heller et al. do not disclose astrand displacement amplification method.

Walker et al. a disclose strand displacement amplification method for generating target nucleic acid sequence (See the Abstract).

One of ordinary skill in the art would have been motivated to apply a strand displacement amplification method as taught by Walker et al. because the method demonstrates increased sensitivity, provides more freedom in choosing target nucleic acid sequences for amplification and shortens time involved in amplification (See column 7, lines 22-30). It would have been prima facie obvious to apply the strand displacement amplification method of Walker et al.

Summary

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung JT
May 8, 2006

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

5/15/06